

INDICATIONS AND USAGE

OCTAGAM 10% is indicated for the treatment of chronic immune thrombocytopenic purpura (cITP) in adults and dermatomyositis (DM) in adults. For patients with cITP, it is used to rapidly increase the platelet count in the blood to help control or prevent bleeding. For patients with DM, it helps improve muscle function and skin rash.

OCTAGAM 10% is a liquid medication that contains Immunoglobulin G (IgG). OCTAGAM 10% is made from human plasma donated by healthy people. OCTAGAM 10% is given through the vein (intravenously) in a hospital, infusion center, or at home.

SELECTED SAFETY INFORMATION

• Do not use OCTAGAM 10% if you have had a severe allergic reaction to IgG or other blood products or have deficiencies of immunoglobulin A (IgA) with antibodies to IgA.

IVIq=intravenous immunoglobulin.

Please click here for Full Prescribing Information, including complete BOXED WARNING.



Free mobile support app for patients. See inside for details.

What is dermatomyositis?

Dermatomyositis (dur-muh-toe-my-uh-SY-tis) is a rare autoimmune disorder that causes rash, joint pain, and muscle weakness. You may hear dermatomyositis called by a more general name that refers to a group of disorders that cause muscle weakness: idiopathic inflammatory myopathy.

Symptoms can vary from person to person and can appear in different areas of the body. They may appear slowly, or all at once. Sometimes your symptoms can disappear for a while, then return.

Dermatomyositis most often occurs in adults in their late 40s to 60s.

Dermatomyositis may cause skin and joint problems, as well as permanent damage to muscles. It is important to speak with your healthcare professional about treatment.

Symptoms of dermatomyositis



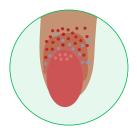
Muscle weakness



Joint pain



Rash Eyelids, chest, upper back



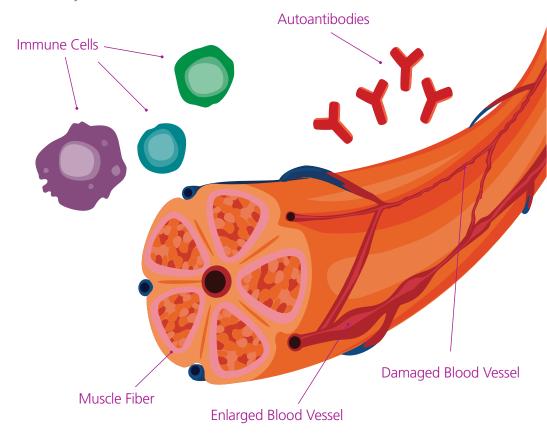
Discoloration Fingers, cuticles, thighs



Red or violet bumps Fingers, elbows, knees, ankles

What causes dermatomyositis?

There are certain cells in the body called immune cells that fight off infection and disease. When a person has dermatomyositis, some of the body's immune cells may release antibodies, which can attack the healthy blood vessels that supply blood to your muscles. This action may produce inflammation and cause dermatomyositis.



Managing inflammation

There is no cure for dermatomyositis, but your healthcare professional can prescribe treatments to manage your symptoms. These may include:

- IVIg: Provides extra antibodies to the blood to help block the autoantibodies
- Steroids: Help reduce inflammation and relieve symptoms
- Steroid-sparing immunosuppressants: Used when steroids do not work or cause unwanted side effects

Because of the range of symptoms you might be experiencing, your care team may include specialists like neurologists, rheumatologists, dermatologists, pharmacists, and nurses, among others.



OCTAGAM 10% is the first and only FDA-approved IVIg treatment for dermatomyositis in adults

In a clinical study, 95 adults with dermatomyositis were given OCTAGAM 10% or placebo.

Patients in both treatment groups could continue taking their other medications while they were part of the study.



This study looked at patient improvements in:

- Muscle strength
- Amount of visible rash
- Activity level
- Quality of life
- Protein levels in muscle

SELECTED SAFETY INFORMATION (CONTINUED)

- OCTAGAM 10% can cause the following:
 - Blood clots in your heart, brain, lungs or other areas of your body
 - Kidney problems, or kidney failure
- Tell your healthcare provider (HCP) if you have an allergy to corn. OCTAGAM 10% contains a type of sugar that is made from corn.

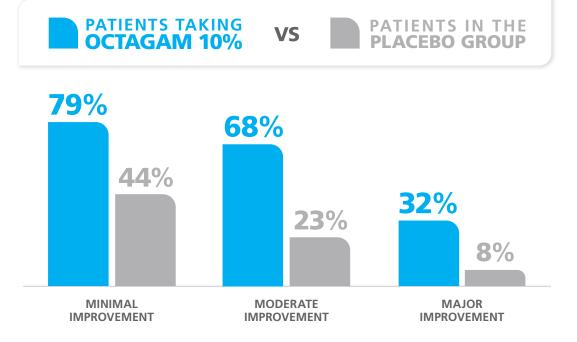
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OCTAGAM 10% was shown to help improve symptoms of dermatomyositis

How was improvement measured?

THERE WERE 3 DIFFERENT CATEGORIES THAT DEFINED HOW MUCH SYMPTOMS IMPROVED: MINIMAL, MODERATE, AND MAJOR

All 3 improvement categories were measured after 16 weeks.



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How will I receive OCTAGAM 10%?

OCTAGAM 10% is given intravenously (through a needle inserted in a vein)

Patients in the clinical study received their infusion over 2 to 5 days. Your infusion may be given either at an infusion clinic or in your own home and will usually be given every 4 weeks.

GETTING READY FOR YOUR INFUSION



Make sure to drink a lot of water the day before and the day of your IVIg therapy, and avoid caffeine and alcohol



Have an activity available to help pass the time (e.g., reading a book)

DURING AND AFTER YOUR INFUSION



Your IVIg therapy will be given through a needle inserted into your vein



Your blood pressure and temperature will be checked during treatment



Your infusion time will vary and could take several hours



You can continue with the regular activities of your day, as tolerated



Call your doctor, nurse, or pharmacist with any questions, or if you have side effects

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Most common drug-related side effects

In a clinical study, more than 5% of patients had the following side effects:

• Headache: 42%

• Fever: 19%

• Nausea: 16%

Vomiting: 8%

• Chills: 7%

• Muscle pain: 7%

Increased blood pressure: 6%



SELECTED SAFETY INFORMATION (CONTINUED)

- OCTAGAM 10% can cause the following serious side effects. Contact your HCP if you experience the following:
 - Swelling in your mouth or throat, hives/itching, breathing problems, wheezing, fainting, tightness in your chest, or dizziness. This could be a serious allergic reaction.
 - Decreased urination, swelling in your legs, sudden weight gain, or breathing problems, which could mean kidney failure

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How is OCTAGAM 10% made?

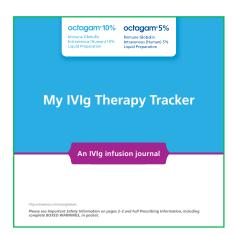
OCTAGAM 10% is made of healthy human plasma, which comes from blood. IVIg therapies like OCTAGAM 10% are made under strict Food and Drug Administration (FDA) guidelines to ensure they're safe to use. These include:

- Getting human plasma from FDA-approved donation centers
- Checking plasma donors for prior exposure to certain viruses and other diseases
- Testing the collected plasma to help ensure that it is virus- and disease-free
- Virus inactivation/removal steps in the manufacturing process

Play an active role in your treatment with the therapy tracker

The OCTAGAM 10% Therapy Tracker is meant to help you track details about your treatment. After each infusion, take some time to take notes about your experience. By sharing this information with your care team, you can work together to make changes as needed.

Ask your healthcare provider or specialty infusion pharmacy how to get your therapy tracker.





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SELECTED SAFETY INFORMATION (CONTINUED)

- Pain and/or swelling of an arm or leg with warmth in the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens with deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body; these could be signs of a blood clot.
- Yellow skin or eyes, dark-colored urine, fatigue, or increased heart rate, which could be signs of a blood problem.
- Headache, stiff neck, drowsiness, fever, sensitivity to light, painful eye movements, or nausea and vomiting, which could mean an inflammation of the membranes covering your brain or spinal cord
- Trouble breathing, chest pain, blue lips, arms or legs, and fever, which could be related to a lung problem. This typically occurs 1 to 6 hours following infusion.

Common side effects include headache, fever, nausea, vomiting, increased blood pressure, chills, musculoskeletal pain, dyspnea, infusion site reactions, and increased heart rate.

If you use a blood glucose monitor, check with your HCP to ensure that your monitor and test strips are acceptable to use while you are receiving OCTAGAM 10%.

These are not all of the possible side effects with OCTAGAM 10%. Tell your HCPs about any side effects that you have that cause concern or don't go away.







Pfizer is committed to providing tools and resources to help support patients on Ig therapy

Ig Companion is a free mobile app designed to complement the treatment experience for patients and caregivers and help prepare them for doctor visits

Please click <u>here</u> for Full Prescribing Information, including complete BOXED WARNING.



Key features of the Ig Companion free mobile app include helping patients:



Navigate through the infusion process



Access educational content



Track, manage, and export infusion information



Set reminders for events



Ig Companion is not intended for curing, treating, seeking treatment for, managing, or diagnosing a specific disease, disorder, or any specific health condition. Pfizer will not have access to any personal information you enter into Ig Companion.

Available for free download from the App Store and Google Play.





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Why OCTAGAM 10%?

OCTAGAM 10% has been shown to improve dermatomyositis symptoms in a clinical study

• Almost twice as many patients taking OCTAGAM 10% saw improvement in their symptoms (79%) when compared with patients taking placebo (44%)

OCTAGAM 10% is the first and only FDA-approved IVIg therapy for dermatomyositis in adults

Patients should always ask their doctors for medical advice about adverse events.

You may report an adverse event related to Pfizer products by calling 1-800-438-1985 (US only). If you prefer, you may contact the US Food and Drug Administration (FDA) directly. The FDA has established a reporting service known as MedWatch where healthcare professionals and consumers can report problems they suspect may be associated with the drugs and medical devices they prescribe, dispense, or use. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

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